UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

WEST HARLEM ENVIRONMENTAL ACTION and NATURAL RESOURCES DEFENSE COUNCIL, INC.,	04 Civ. 8858 (JSR)
Plaintiff,	MEMORANDUM ORDER
-v-	
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,	
Defendants.	

JED S. RAKOFF, U.S.D.J.

Plaintiffs West Harlem Environmental Action and the Natural Resources Defense Council, Inc. seek declaratory and injunctive relief against the United States Environmental Protection Agency ("EPA"), alleging that EPA's decision in 2001 to revoke certain child safety measures on rodenticides that EPA had put in place in 1998 violated both the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq., and the Administrative Procedure Act ("APA"), 5 U.S.C. § 500 et seq. Both sides have moved for summary judgment. For the reasons that follow, each motion is granted in part and denied in part, and, as a result, the case is remanded in part to the EPA.

FIFRA requires pesticides to be "registered," or licensed, before they are distributed or sold. 7 U.S.C. § 136(a) (setting forth procedure for registration). Before a pesticide can be registered, the EPA administrator must determine, among other things, that the pesticide "will perform its intended function without unreasonable adverse effects on the environment." 7 U.S.C. §

136a(5)(C). The phrase "unreasonable adverse effects on the environment" includes "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. 136(bb). Rodenticides are pesticides and are accordingly covered by FIFRA. 7 U.S.C. § 136(t) and (u).

In 1988, Congress amended FIFRA to require EPA to reregister, with some exceptions not here relevant, "each registered pesticide containing any active ingredient contained in any pesticide first registered before November 1, 1984." 7 U.S.C. § 136a-1. As with registration, reregistration requires that the EPA administrator determine that the pesticide "will perform its intended function without unreasonable adverse effects on the environment." 7 U.S.C. § 136a-1(g)(2)(C) (incorporating requirements of § 136a(5)(C)). According to the EPA:

> When EPA completes the review and risk management decision for a pesticide that is subject to reregistration (that is, one initially registered before November 1984), the Agency generally issues a Reregistration Eligibility Decision or RED document. The RED summarizes the risk assessment conclusions and outlines any risk reduction measures necessary for the pesticide to continue to be registered in the U.S.

See EPA, Pesticide Tolerance Reassessment & Reregistration (last updated Sept. 14, 2004), available at http://www.epa.gov/pesticides/reregistration.

Two REDs issued by the EPA in 1998 and revised in 2001 are the subject of the instant lawsuit. The "Rodenticide Cluster" RED

covered the ingredients brodifacoum, bromadiolone, chlorophacinone, diphacinone, bromethalin, and pival. Administrative Record ("Rec.") 193-539. The "Zinc Phosphide" RED covered the ingredient zinc phosphide. Rec. 540-777. Each RED consisted of hundreds of pages analyzing and assessing, inter alia, the physical chemistry of the rodenticides, the effect of the rodenticides on human health (focusing especially on their toxicity and results of accidental exposures), and the effect of the rodenticides on the environment. Each RED was accompanied by detailed appendices. Rec. 193-539, 540-777.

As part of the decision to reregister the rodenticides covered by these two REDs, the EPA designed a variety of measures to mitigate the risks associated with the rodenticides. Rec. 329-33, 600-06. In Phase I of the risk mitigation process, EPA required improved labeling and the annual submission of poison control data, and restricted the use of certain formulations of the rodenticides. Rec. 330-32, 602-03. EPA also imposed as part of Phase I the two mitigation measures at issue here: each rodenticide would have to contain, first, an indicator dye that would help identify whether children or pets had consumed a rodenticide by dying their mouths and/or hands a bright color, and, second, a bittering agent whose bitter taste would reduce the amount of bait consumed by children and pets. Rec. 330, 337, 601, 607. The REDs did not impose a date by which the indicator dye and bittering agent had to be incorporated into the rodenticides, stating that "the Agency will work with

registrants to establish a time frame" for such incorporation but that it would be some point prior to the initial meeting of the "stakeholder group" whose formation constituted Phase II of the risk mitigation process. Rec. 337, 607.

This stakeholder group, eventually called the Rodenticide Stakeholder Workgroup ("RSW"), see Rec. 1078, was designed to bring together rodenticide registrants, state regulators, poison control centers, rodent control experts, members of the environmental community, and medical professionals "to discuss means of significantly reducing exposures to children and pets," Rec. 333, and "to decide on specific timing and other issues associated with bait dyes, bittering agents, and the content of a special label warning to users of rodenticides that children are particularly vulnerable to ingestion of baits," Rec. 602. Consultation with the RSW was to conclude approximately nine months after the issuance of the REDs, and EPA expected at that time "to have a recommendation on how to further mitigate risk to children and household pets and an implementation plan to achieve significant risk reduction." Rec. 333, 602.

EPA selected 26 members, drawn from the intended array of groups, to participate in the RSW. Rec. 1084-85, 1113-16. The RSW met five times between the months of March and October 1999. Rec. 1081, 1086-93. On November 15, 2000 the RSW submitted a 35-page report to the Pesticide Program Dialogue Committee ("PPDC") for ultimate consideration by EPA, accompanied by hundreds of pages of appendices that included, inter alia, all the written materials

considered by the RSW in reaching its recommendations. Rec. 1076-1111, 1112-1545. In this report, the RSW recommended that EPA not require the two child safety measures at issue here. Rec. 1105-07. As to the indicator dye, the report briefly discussed several difficulties in finding a suitable dye, and concluded that the technology to produce a suitable indicator dye was not yet available. Rec. 1105. As to the bittering agent, the report expressed concerns that the inclusion of a bittering agent would reduce bait acceptance by the targeted rodents, and noted that, despite the success of some bittering agents in EPA laboratory tests, some RSW members believed, based on their experience, that such agents did not work as well in real world situations. Rec. 1106-07. The RSW report recommended, therefore, that both the indicator dye and bittering agent no longer be required in a registered rodenticide, but that further research be done on finding a suitable indicator dye and that EPA allow manufacturers to include the indicator dyes and bittering agents on a voluntary basis. Rec. 1105, 1107, 1110-11.

Subsequently, on November 28, 2001, EPA published in the Federal Register an Amendment to the Rodenticide Cluster and Zinc Phosphide Reregistration Eligibility Decision (RED) Documents ("Amendment"), Rec. 3044-3046, that rescinded the bittering agent and indicator dye requirements. Rec. 3044. Only two paragraphs of the three-page Amendment actually explained the reasons for the decisions to rescind. Those paragraphs read:

> The Rodenticide Cluster and Zinc Phosphide REDs concluded that the rodenticide bait would not be eligible for reregistration without including an indicator dye and

> bittering agent into the formulations of all rodenticide baits. These indicator dyes were expected to show whether a child had come into contact with the bait by leaving a stain on a child's mouth or hands. By staining the hands, mouth, etc., of an exposed child, EPA believed that such an indicator dye would confirm whether a child ingested or handled any rodenticide bait. The recommendation of the RSW was to drop this requirement from the RED due to the lack of suitable dye. Other issues of concern included: (1) There are no data on indicator dyes as an adequate marker; (2) the dye's effect on the overall efficacy of the product; (3) potential cost of new efficacy testing; (4) distinguishing between stains on a child from food products and stains from indicator dyes; (5) finding a dye that was temporary; and (6) contending with inevitable property damage resulting from contacted surfaces. Some members of the RSW felt that if technology was available, indicator dyes might have merit in managing potential exposure cases. Additional research and development, however, is needed before implementing such a requirement.
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> The REDS also concluded that a bittering agent be incorporated into the formulations of all rodenticide baits with the intention of minimizing the amount of bait accidentally ingested. In theory, a bittering agent would prevent a child from taking more than one mouthful, thereby possibly limiting the magnitude and severity of the exposure. The RSW recommended dropping the bittering agents as a mandatory requirement. Rodents have the ability to taste bittering agents raising the potential for bait acceptance problems. RSW members associated with urban rat control programs strongly believed that bittering agents adversely affect the efficacy of rodenticide baits. Another point of contention was EPA's reluctance to allow registrants of products containing bittering agents to make representations on the labeling about the bittering agent as a safety feature. Federal regulations prohibit making safety claims on pesticide labeling. (See 40 CFR 156.10(a)(5)(ix)). Also, inclusion of the bittering agent does not make the bait less toxic nor does it provide absolute protection for children.

Rec. 3045-46.

The Amendment added that, "[w]hile the RSW recommended dropping indicator dyes and bittering agents as mandatory requirements, members also recommended that EPA allow industry to retain the option of including such ingredients in rodenticide bait products on a

voluntary basis." Rec. 3046. "Therefore," the Amendment concluded, "based on the findings presented to the PPDC by the RSW, EPA has determined that the rodenticide bait products are eligible for reregistration without indicator dyes and bittering agents. Although indicator dyes and bittering agents may not be necessary in all cases, EPA supports voluntary incorporation of these ingredients in rodenticide formulations." Id.

On November 9, 2004, plaintiffs filed the instant lawsuit pursuant to 7 U.S.C. §§ 136n(a) and 136n(c) (granting district courts jurisdiction to enforce FIFRA), alleging, in the first count, that EPA's 2001 reregistration of the rodenticides in question without the previously required mitigation measures causes "unreasonable adverse effects on the environment" in violation of FIFRA, 7 U.S.C. §§ 136a(c)(5)(C), 136a-1(g)(2)(C), and 136(bb), and, in the second count, that such reregistration therefore constitutes arbitrary and capricious agency action in violation of the APA, 5 U.S.C. § 706(2)(A). However, because the APA does not provide its own cause of action but merely states the scope of review under FIFRA, see Defenders of Wildlife v. Administrator, EPA, 882 F.2d 1294, 1303 (8th Cir. 1989), the stand-alone APA claim (the second count) must be dismissed, as plaintiffs themselves now concede. See transcript, 6/6/05 at 2. By the same token, however, consideration of plaintiff's first count requires analysis of whether EPA's action under FIFRA was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A).

In conducting such an analysis, a court must first ascertain whether the agency "examined the relevant data and articulated a satisfactory explanation for its action including a rational connection between the facts found and the choice made." Motor Vehicle Mfrs' Ass'n of the United States, Inc. v. State Farm Mutual Automobile Ins. Co., 463 U.S. 29, 42 (1983) ("State Farm"). An agency action will be deemed arbitrary and capricious where "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." Id. at 43 (internal quotations and citations omitted).

In conducting such a review, the Court should as a general matter defer to the agency's expertise in scientific and technical matters, see Riverkeeper, Inc. v. United States Environmental Protection Agency, 358 F.3d 174, 184 (2d Cir. 2004), and not substitute its judgment for that of the agency, State Farm, 463 U.S. at 43. However, where, as here, the challenged agency action is an agency reversal of a prior action,

> a court must satisfy itself that the agency knows it is changing course, has given sound reasons for the change, and has shown that the rule is consistent with the law that gives the agency authority to act. In addition, the agency must consider reasonably obvious alternatives and, if it rejects those alternatives, it must give reasons for the rejection, sufficient to allow for meaningful judicial review. Although there is not a heightened standard of scrutiny, the agency must explain why the original reasons for adopting the rule or policy are no longer dispositive. Even in the absence of cumulative experience, changed

> circumstances or judicial criticism, an agency is free to change course after reweighing the competing statutory policies. But such a flip-flop must be accompanied by a reasoned explanation of why the new rule effectuates the statute as well as or better than the old rule.

New York Council, Ass'n of Civilian Technicians v. Federal Labor Relations Authority, 757 F.2d 502, 508 (2d Cir. 1985) (internal quotation and citations omitted); see also State of New York Dep't of Social Svcs. v. Shalala, 21 F.3d 485, 492 (2d Cir. 1994) ("An agency's new position is entitled to substantial deference so long as 'there appears to have been good reason for the change.'").

Applying these standards to the rescinding of the indicator dye requirement, plaintiffs contend that, contrary to EPA's conclusion in the Amendment, suitable dyes do in fact exist and were known to the EPA. In support of this assertion, they point to the EPA's statement in one of the original REDs that it "recognizes that many of the formulations currently contain a dye. All registrants may present data demonstrating that the current dye meets the intent of this requirement." Rec. 330. However, an invitation to submit data on suitable dyes is not the same as a conclusion that suitable dyes exist. On the contrary, such submissions may well have shown that none of the proffered dyes was suitable. Indeed, there is evidence in the record that this is what the EPA found. See, e.g., Rec. 2078, 2089, 2257. Similarly, while the EPA stated in the original REDs that "[p]ossible indicator dyes include FD&C Blue No. 1 and FD&C Red No. 3," Rec. 2233, a speculation as to which dyes might serve the intended function is hardly the same as a determination that they do. Plaintiffs' reference to the statement of a California county

agricultural commissioner who submitted comments on the safety requirements that "[i]ndicator dyes are already a requirement and have not been a problem here in California," Rec. 2081, is no more compelling, since the California law there referred to prescribes, not the kind of indicator dyes here in issue, which are designed to stain the skin of a child who mistakenly ingests the pesticide, but rather visually evident dyes, designed to make the pesticide stand out. Title 3, Cal. Code Regs., § 6180. Indeed, the California Department of Food and Agriculture elsewhere concurred that the technology for developing a suitable indicator dye of the kind here in issue is not yet available. Rec. 2890, 2897-98.

Plaintiffs' fall-back position is to argue that the EPA missed an opportunity for certain types of data collection by not including the issue of indicator dyes as a stand-alone line item on agendas of various conference calls and in-person meetings in the record; but these agendas are, for the most part, written at a high level of generality, and mere speculation that the absence of any specific line item means that it was not discussed is not adequate to establish any failure on the part of EPA. Rec. 1121-27.

On balance, then, there was sufficient evidence in the record to support EPA's conclusion that the indicator dye requirement should be rescinded for lack of a suitable dye. While the Amendment could have set this rationale forth with greater clarity, "the agency's path may reasonably be discerned" from even the thin discussion offered there. Torrington Extend-A-Care Employee Association v. NLRB, 17 F.3d 580, 590 (2d Cir. 1994) (quoting State Farm, 463 U.S. at 43).

Accordingly, EPA's decision to rescind the indicator dye requirement must be upheld.

The same cannot be said of the decision to rescind the bittering agent requirement. The primary record evidence on which EPA seems to have based its decision to withdraw this requirement is an informal report of a field study conducted by the City of Chicago in 1994 after the city noted an increase in the rat population and learned that the manufacturers of the rodenticide it had been using for years had recently added a bittering agent. Rec. 1196-1232. The report of the Chicago study is long on rhetoric but short on analysis. On any fair reading, it provides no reasonable basis for concluding that there is a causal relationship between the addition of the bittering agent and the increased rat population. Indeed, the report itself recognized as much. See Rec. 1228 (acknowledging that "[r]esults of the field study would be inconclusive at this time"). The EPA's reliance on the Chicago report was additionally problematic because the EPA failed to investigate the methodology and evidence underlying what is essentially an anecdotal report, for example, by requesting specific data or by interviewing any of the officials involved with the underlying field study.

The few additional snippets on which the EPA relied in reaching its conclusion to rescind the bittering agent requirement are likewise lacking in probative value. The EPA makes reference to a 1992 summary report that reviewed studies from the 1970s and 1980s that in turn suggested a possible link between rodent "shyness" and a bittering agent added to a bait. But nowhere does the EPA explain

why this summary was any more compelling at the time of the 2001 Amendment than it was at the time of the 1998 REDs (which reached the opposite conclusion), let alone whether the science it reviews is still up to date. See Rec. 1413. No more rational was the EPA's reliance on a handful of public comments expressing the view that bittering agents are ineffective, since the EPA made no attempt to inquire as to the evidence, if any, supporting these conclusions. Rec. 2432.[1]

In short, the EPA lacked even the proverbial "scintilla" of evidence justifying its reversal of the requirement it had imposed, after extensive study, only a few years before. See, e.g., Rec. 113I (reviewing literature on scientific studies supporting efficacy of bittering agents).

Furthermore, even assuming arguendo that the record somewhere provided the requisite scintilla of evidence to support the EPA's conclusions, the Amendment's explanation would still be inadequate. State Farm, 463 U.S. at 52. The few sentences in the Amendment that purport to explain the reason for the agency's reversal of the

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[1] It may also be noted that several industry groups expressly approved of the bittering agent requirement, a position they would hardly have been expected to take if the inclusion of bittering agents undermined the efficacy of their products. See Rec. 2088 (rodenticide registrant indicating that "incorporation of a bittering agent is a positive step to reduce the likelihood of accidental ingestion" and that it would "shortly submit alternative formulas containing a bittering agent for approval by the agency"); Rec. 2258 (industry lobbying group stating that "[a]s a group ... we believe that the addition of a bittering agent to those products that are primarily used in the home is a reasonable approach to take" and that "[i]n fact, the addition of bittering agents was initiated by industry many years ago.").

bittering agent requirement largely consist of references to a presumed "potential" for reduced bait acceptance and the "strong beliefs" of certain RSW members that such a potential has been realized. Such ipse dixit cannot take the place of analysis of whether these beliefs were reasonable or whether the "potential" was actually realized.[2] Indeed, if there were anything to these conclusions, it logically would have led the EPA to discourage the use of such bittering agents because of their negative effects. Yet the Amendment, even while reversing the requirement that bittering agents be included, goes on to permit or even encourage their voluntary use.

Nor does the Amendment explain any alternative mitigation measures that the EPA considered to take the place of the bittering

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[2] Plaintiffs' amici, the States of New York and California, draw the Court's attention to the many rodenticides available for use in those states that contain a bittering agent, arguing that EPA either had efficacy data on these rodenticides or had the statutory authority to obtain such data, and that EPA's failure to make use of this data, which would have supported the proposition that the bittering agents did not make the products less efficacious, was arbitrary and capricious. See Memorandum Of Amicus Curiae State Of New York In Support Of Plaintiffs' Motion For Summary Judgment at 6 n.11; Brief Of Amicus Curiae Bill Lockyer, Attorney General Of California, In Support Of Plaintiffs' Motion For Summary Judgment at 10 and Ex. B. In response, the EPA contends that the Court may not properly consider this extra-record evidence in the absence of a "strong showing in support of a claim of bad faith or improper behavior on the part of agency decisionmakers." Nat'l Audobon Soc. v. Hoffman, 132 F.3d 7, 19 (2d Cir. 1997). Although the Court agrees with the EPA that the Court's review in this case is confined to the administrative record, the thrust of the States' submissions, with which the Court also agrees, is that there existed obvious data responsive to the key question of whether a bittering agent deters a rodenticide's effectiveness that the EPA, inexplicably, chose to ignore.

agent requirement it was withdrawing. See New York Council, 757 F.2d at 508. Likewise, the Amendment also fails to demonstrate that, in withdrawing the bittering agent requirement, the EPA considered all of the statutorily-mandated factors. See 7 U.S.C. § 136(bb).

In short, the Amendment does not come close to providing a "reasoned explanation of why the rew rule effectuates the statute as well as or better than the old rule." See New York Council, 757 F.2d at 508.

Finally, the Amendment is problematic so far as the bittering agent reversal is concerned because it demonstrates an uncritical acceptance of the RSW report rather than the careful weighing of the evidence that was EPA's responsibility. See, e.g., Sierra Club v. Lynn, 502 F.2d 43, 59 (5th Cir. 1974) (agency may not "abdicate its statutory duties by reflexively rubber stamping a statement prepared by others" but instead "must independently perform its reviewing, analytical and judgmental functions"). The paragraphs of the Amendment that explain the decision to withdraw the bittering agent requirement merely summarize the RSW recommendations without analyzing whether the RSW got it right. The Amendment begins with the striking statement that "the Agency came to a mutual agreement with the rodenticide registrants to rescind the bittering agent and indicator dye requirements from the RED." Rec. 3044. Yet, while an objective reason is given for accepting this consensus so far as the indicator dye is concerned -- to wit, no such dye exists -- the thrust of the explanation regarding the bittering agent is simply that the RSW reached a compromise that the inclusion of such an agent

should be left to the discretion of manufacturers. See Rec. 2826. EPA is not in the business of reaching consensus with the "stakeholders" it regulates. EPA's job is independent review, and there is no indication here that EPA fulfilled that role so far as the bittering agent is concerned.

Accordingly, for the foregoing reasons, plaintiffs' motion for summary judgment is granted as to the withdrawal of the bittering agent requirement and defendant's motion is granted as to the withdrawal of the indicator dye requirement. In other words, the EPA's rescinding of the indicator dye requirement is affirmed and the EPA's rescinding of the bittering agent requirement is reversed and remanded to the EPA for further consideration consistent with this opinion.

SO ORDERED.

JED S. RAKOFF, U.S.D.J.

Dated: New York, New York
August 7, 2005